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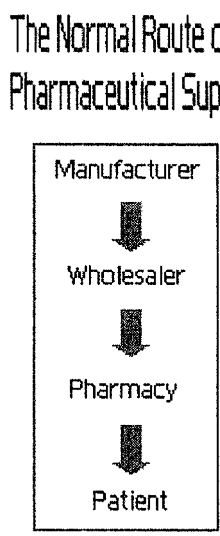
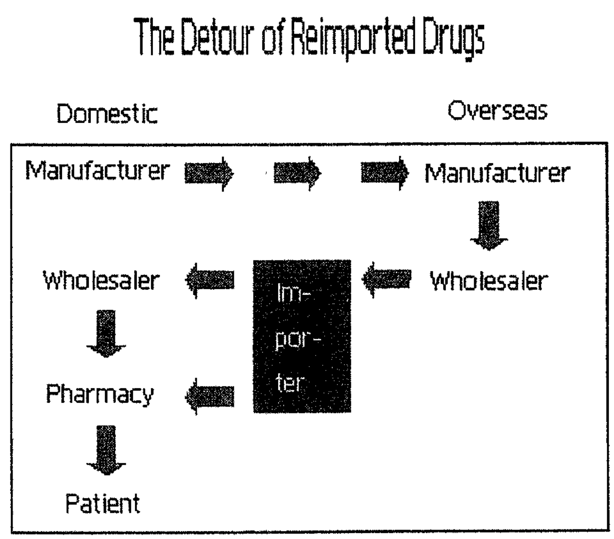
German Association of Research-based Pharmaceutical Manufacturers (VFA)

Parallel Trade and Reimportation in the Pharmaceutical Market: Misguided Health Policy

What is parallel trade and what are reimported drugs?

Parallel imports and reimported drugs ("reimports" for short) are pharmaceuticals that are meant for and packaged for a foreign market, but that don't reach patients there; instead, they are purchased by special import businesses and are brought to market in Germany. Given that the original product already had approval in Germany, either a streamlined process or – if already approved in Europe - no approval process at all is required for the reimported medicines. The importer need only replace the foreign text on the packaging and on the product insert. However, the foreign text can remain on the outer packaging.



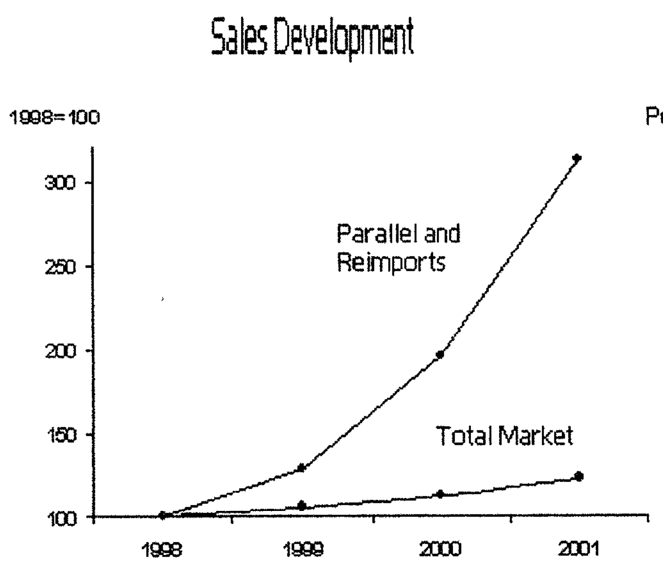


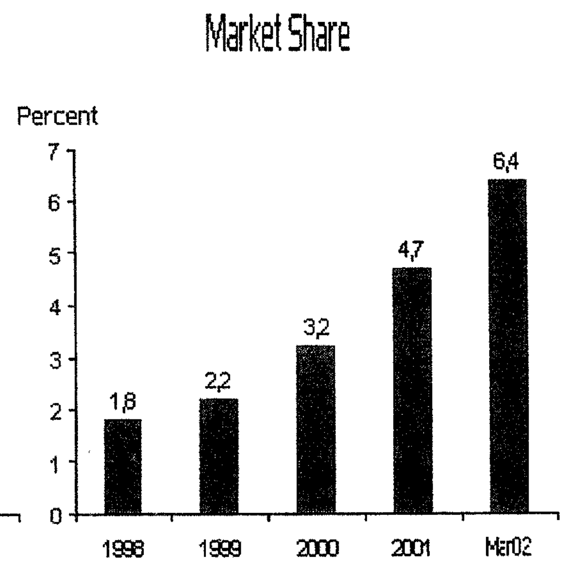
The economic incentive for reimportation comes from the difference in international prices. It is possible to acquire a drug at a cheap price overseas and, for example, to sell it for a higher price in Germany.

Differences in international prices develop primarily through price regulation overseas. Special national price-setting systems exist in many European countries, which artificially hold down the cost of drugs. National price-setting is oriented primarily at the economic capability of a nation's own economy. This leads to a situation in which, for example, in southern European countries many – although in no way all – medicines are cheaper than in northern European countries.

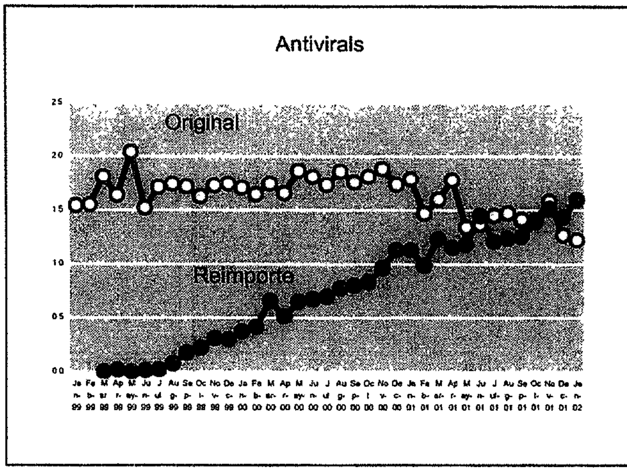
How has trade in reimported medicines developed in Germany?

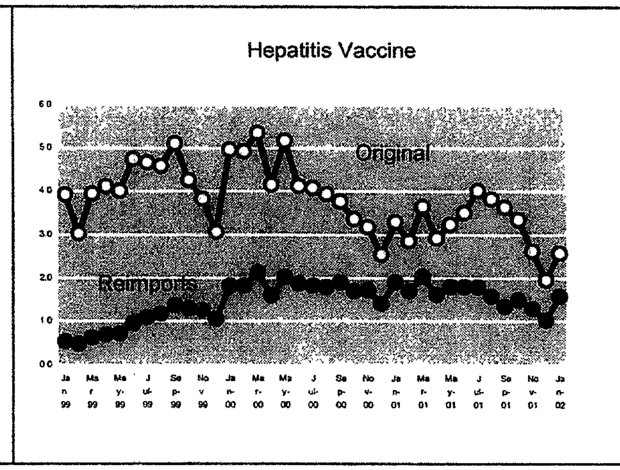
In the past four years – particularly beginning in 2000, reimports in Germany have experienced high growth. From 1998 to 2001 the earnings from reimports alone in the pharmacy market more than tripled (from manufacturers' prices of around 260 million euros to over 800 million euros). The growth is also continuing uninterrupted this year. The market share of reimports increased from 1.8% in 1998 to 5.8% in January 2002.

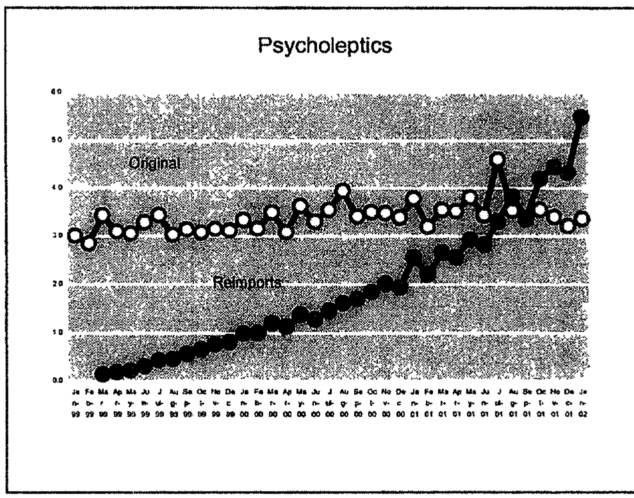


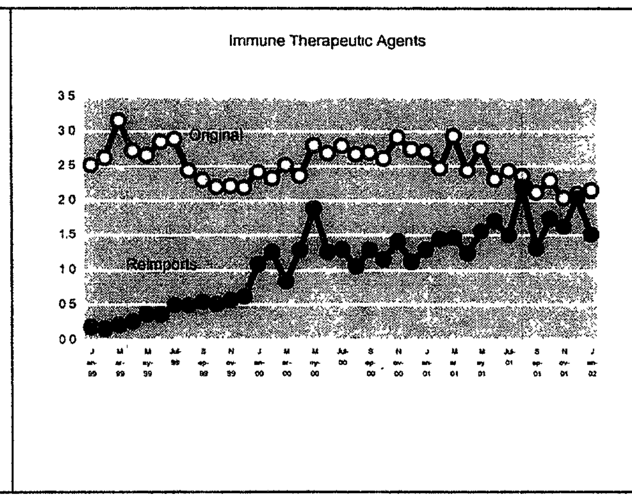


The earnings from reimported medicines have, in many cases, already overtaken the earnings of the originals. The following example of four of the highest-earning imported medicines demonstrates this development.









The upswing of reimports did not occur due to normal market conditions, but is to be traced back to state support. Reimports are directly supported via legal rules and distribution contracts between pharmacies and health insurance companies. Section 129 paragraph 1 of the Social Law V obliges pharmacies to dispense low-priced imported pharmaceuticals. The agreement obliges pharmacies to meet a minimum quota of 5.5% reimports in 2002 and of 7% in 2003 per pharmacy. A guaranteed growth in earnings does not exist in any other branch.

Are reimported drugs actually cheaper?

The targeted support of reimports through legal requirements was conditioned upon the imported medicine being at least 10% cheaper than the original. Consequently, the prices were, as a rule, set by reimporters such that this precise difference would be maintained. This relationship is clearly seen as unalterable, since the latest regulations declined to allow for a minimum difference (Section 129 paragraph 1 Social Law V and the decision of the "Schiedstelle" according to Section 129 paragraph 8 SGB V).

The current development of import prices demonstrates that the price differences that existed in the past were by no means "natural law". As the following prices show, the difference in price between originals and reimports have markedly shrunk. It is telling that the prices for eight of the previously most important products fell to about 17% of reimported earnings in 2001. In none of the examples was the earlier price difference of 10% achieved. The maximum difference was 6%, but half of the products had a difference of only 3% or less. In as much as the changes in prices over the last three years can be analyzed, the increases in price by the importers lie without exception above the increases in price by the manufacturer.

Reimports: Differences in Price are Retroactive

Price Examples of High-Turnover Products

Product	Indication	Pharmacy Selling Price Jan. 2002		
		Original	Reimport	Difference
		Euro	Euro	%
KLACID	Antibiotic	29,61	27,82	6,0
GLUCOBAY	Antidiabetic	45,19	42,90	5,1
NORVASC	Calcium Antagonist	120,48	119,55	0,8
TWINRIX	Hepatitis Vaccine	66,26	62,93	5,0
PROGRAF	Immune Suppressant	489,01	479,23	2,0
ZYPREXA	Psycholeptics	76,75	74,43	3,0
ISCOVER	Platelet Aggregation Inhibitors	240,11	236,45	1,5
COMBIVIR	Antivirals	740,52	715,56	3,4

Source: NDCHealth, VFA

Furthermore, an analysis of prices shows a narrow band width due to weak price competition among importers. The prices of most of the suppliers are either identical or off by just a few cents.

Like every business, import businesses follow economic interests above all else, which is why they are committed to achieving the highest possible price. Via the detour of the products overseas, imports carry transport costs, foreign taxes and provisions that must be covered. Repackaging is an additional significant cost factor. The "value-added" of this branch consists of opening finished pharmaceutical products, swapping the inserts, sticking labels over foreign text, cutting bubble packs (to conform to German-sized bubble packs) and then sealing the packaging again. Added to this are the costs of business in the domestic market.

The additional costs lead to the fact that import businesses concentrate primarily on the highest priced products that are subject to particularly strict price regulation overseas. The selling price of a reimported medicine was on average 30.12 Euros, roughly three times as much as the average price of all drugs.

Can the health insurance companies lower their costs through reimportation?

Dispensing reimports creates an advantage for the health insurance companies as long as they can achieve savings on dispensing the medicines. The health insurance companies saved around 60 million euros in 2001 from the low prices of reimports – roughly .3% of the total spending on pharmaceuticals.

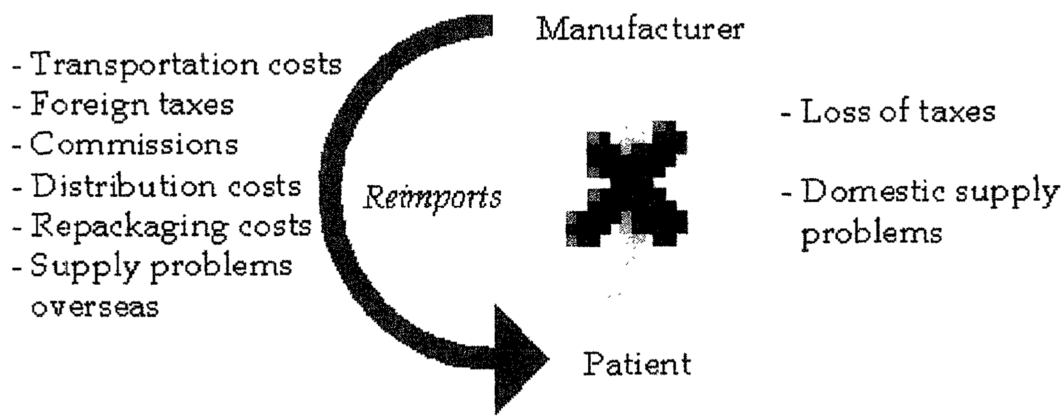
The savings vanish when the imported medicines lead to dosing and usage problems. According to the German Diabetes Society and the Berlin Association of the German Diabetes Federation (Berliner Morgenpost 2.26.02), complaints are growing about reimported insulin products. The Pharmaceutical Commission of the German Pharmacists (AMK) also reports about increasing complaints. Increased difficulties in handling and disruptions in the functioning of insulin pumps through the application of German language labels has led to serious fluctuations in blood sugar and could damage a patients' health. Similar problems with other products are also possible and call into question the cost advantage of reimports to health insurance companies.

A large part of the targeted price advantaged is not passed on to the health insurance companies, but remains with the business. Advertising brochures of the importers indicate that the financial advantage that the pharmacies receive through generous discounts is higher than the savings to the health insurance companies.

What disadvantages does the taxpayer face from reimportation?

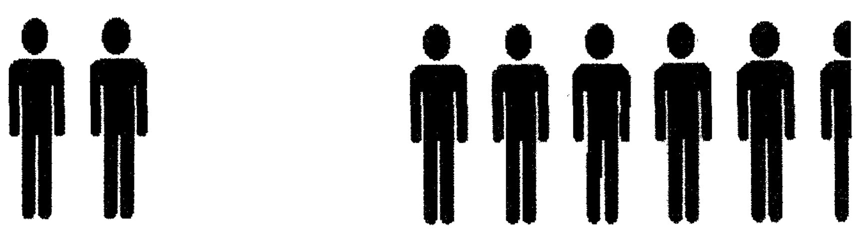
The uncertain savings for the health insurance companies must be considered in light of the considerable damaging effect in other areas of the national economy. Due to the detour of products overseas, the German treasury loses considerable tax income, which importers do not compensate for by means of appropriate tax payments. Instead tax liabilities and additional costs develop abroad which must be covered in the price of imported medicaments.

The Consequences From Reimportation For the Drug Supply



Beyond that, the loss of jobs and the resulting burdens must also be considered. In the long term, no industry can afford to maintain production under domestic cost conditions if it is confronted with a price level from low wage countries. Under such conditions, Germany will not be able to maintain its status as a "production location". Importers are not in a position to compensate for this. The market leader among the importers had earnings of over 500 million euros in 2001 in the pharmacy market alone and employed roughly 1000 people, which translates into approximately one million euros in earnings million euros in earnings for every 5.4 employees.

Employees per Million Euros in Turnover



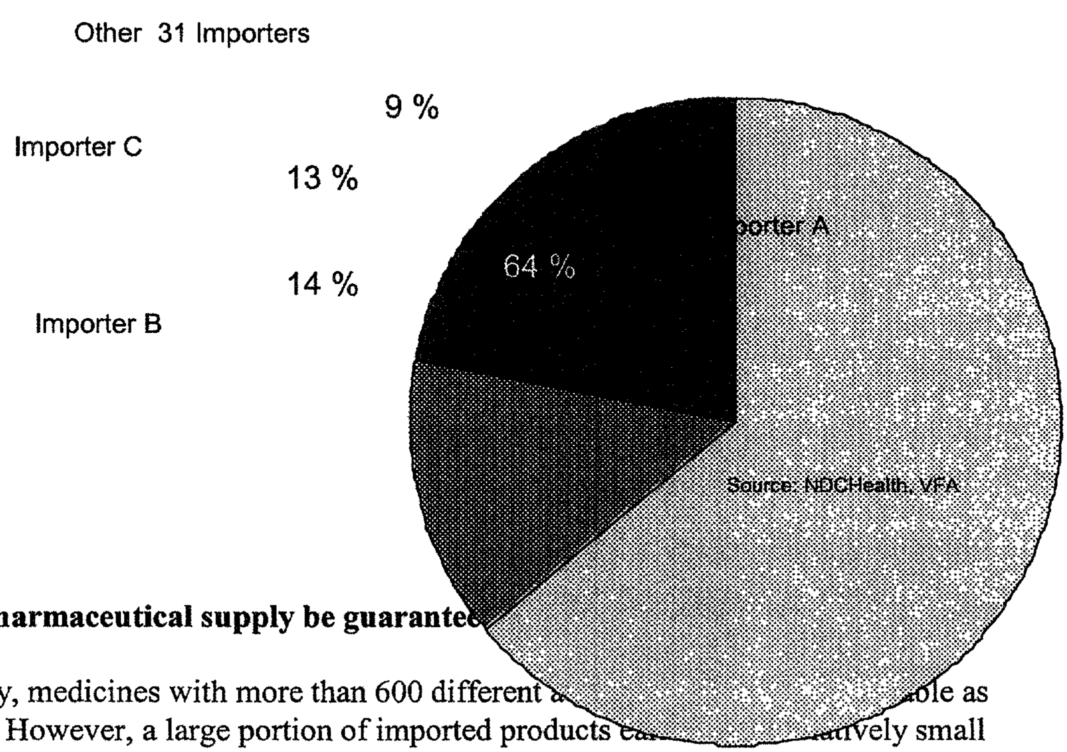
Importer **Productive Industry**

Beyond that, the development and production of pharmaceuticals naturally requires a much higher percentage of highly-qualified workers than does repackaging.

Does reimportation increase competition in the pharmaceutical market?

Currently, there are 35 companies in Germany that specialize in the reimportation of foreign medicines. In contrast to the entire pharmaceutical market, in which the market leader's market share lies below 5%, the partial market of reimports is highly concentrated. Whereas the annual turnover of most importers does not amount to even a million euros, the annual turnover of the largest group of importers is 500 million euros, with a market share of 64%. Two other companies have a market share of 13 and 14%, meaning that more than 90% of the market is allotted to three suppliers. Supporting reimportation does not serve to promote competition.

With the continuation of sales development this year, the largest importer will achieve higher earnings in the pharmacy market than the highest earning productive enterprise. The Federal Government must allow itself to be asked whether it is a positive indication that a repacking company, through state support, arrives at the number one place in the market.



Can the pharmaceutical supply be guarante

In Germany, medicines with more than 600 different ... ble as reimports. However, a large portion of imported products ea... tively small amount. The largest earnings are achieved by only a few products. More than a quarter of the earnings (26.3%) is derived from the reimportation of the top 10 active ingredients. Two thirds of the earnings (66%) are derived from 50 of the top active substances.

Of interest to importers are, above all, products which contain patent-protected active substances. In countries with freer competitive conditions, these products can obtain appropriate prices, which make possible the refinancing of the high esearch and development costs. On the other hand, medicines with active substances whose patent protection has expired are subject to intense price competition by generics in Germany. In this market segment, German prices are often lower than in foreign markets in which competition among generics plays no large role. These medicines are often listed on the offer lists of the importers; however, they are not available in times of necessity. In the statistics of the legal health insurance, there were no regulations in 1999 for 58% of the listed reimported drugs.

Given the selective concentration by the importers on few profit-yielding medicines, a comprehensive domestic pharmaceutical supply cannot be ensured via reimportation. On the other side, the supply in foreign markets is impaired. Since foreign markets are usually much smaller than the German market, the importers create the pressure of demand there that can be higher than the domestic need. Thus, the per person cost of a prominent cytostatic drug is more than twice as high in Greece as it is in Germany. Given that only a portion of the drug remains in that market, the supply of the drug, according to press releases, is endangered in Greece, despite the high price.

From this example it is clear that the principle of free trade in goods, which is anchored in the EEC treaty, can only function if national sub-markets are also structured as free markets. When, in contrast, there are price controls at the national level, free trade leads to the export from these regimes to other countries, causing socio-political distortions.

Conclusions

The current regulations that support reimportation have few advantages for patients, lead to questionable savings in the health insurance system, and endanger Germany as a "production location".

The German Association of Research-Based Pharmaceutical Manufacturers (VFA) therefore demands:

- Limiting national price interventions to the respective domestic markets
- Abolishment of the one-sided preference for imported medicines in Section 129 Paragraph 1 of the Social Law V
- Abolition of the competition-distorting earnings guarantees for importers in the supply contracts between pharmacists and health insurance companies